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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,608	02/06/2004	Michael G. Fisher	021976-000200US	7771

20350 7590 06/27/2006

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EXAMINER
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HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/773,608	<b>Applicant(s)</b> FISHER ET AL.	
	<b>Examiner</b> Mary Hoffman	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 4/12/2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) 81-114 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/6/2004, 4/12/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                                |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/31/2005</u> . | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-80 in the reply filed on 4/12/2006 is acknowledged. The traversal is on the ground(s) that there would be no undue burden on the examiner to search the invention of Group II with Group I since the subject matter of the groups would "substantially overlap". In response to applicant's argument that the search of all the inventions is similar and, thus, the burden on the examiner would not be significant, "a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation of separate classification" (see M.P.E.P. § 808.02). In the instant case, the inventions have separate classifications. The restriction requirement between Group I and Group II is therefore deemed proper. However, the species requirement has been withdrawn after further consideration due to applicants comments that the claims to restricted species must be mutually exclusive.

Claims 81-114 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/12/2006.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Objections***

There exists an inconsistency between the language of claim 1 and that of the claims 30-38 dependent thereon, thus making the scope of the claim unclear. In the claim 1, applicant recites "A device...comprising at least one stationary femoral member...and at least one adjustable femoral member" with the tibial member being only functionally recited, i.e. "movably couplable with at least one tibial member...", thus indicating that the claim is directed to the subcombination, "A device...comprising at least one stationary femoral member...and at least one adjustable femoral member". However, in claims 30-38, applicant positively recites the tibial member as part of the invention, i.e. "wherein the at least one tibial member is engageable.", thus indicating that the combination, a device...comprising at least one stationary femoral member...and at least one adjustable femoral member, and tibial member, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 1-41 will be considered as being drawn to the subcombination, a device...comprising at least one stationary femoral member...and at least one adjustable femoral member.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3733

Claim 73 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 73 recites the limitation "the cut surface" in line 2. There is insufficient antecedent basis for this limitation in the claim. The suggested change is to make claim 70 dependent from claim 43 rather than 42.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26-27, 66-67, and 34, 74 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 26 and 66, applicant positively recites part of a human, i.e. "two apertures extend...to the distal femur". Thus claims 26-27 and 66-67 include a human within their scope and are non-statutory. In claims 34 and 74, applicant positively recites part of a human, i.e. "the femoral member and tibial member are coupled by force provided by the at least one ligament of or adjacent the knee. Thus claims 34 and 74 includes a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In *re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

***Claim Rejections - 35 USC § 102***

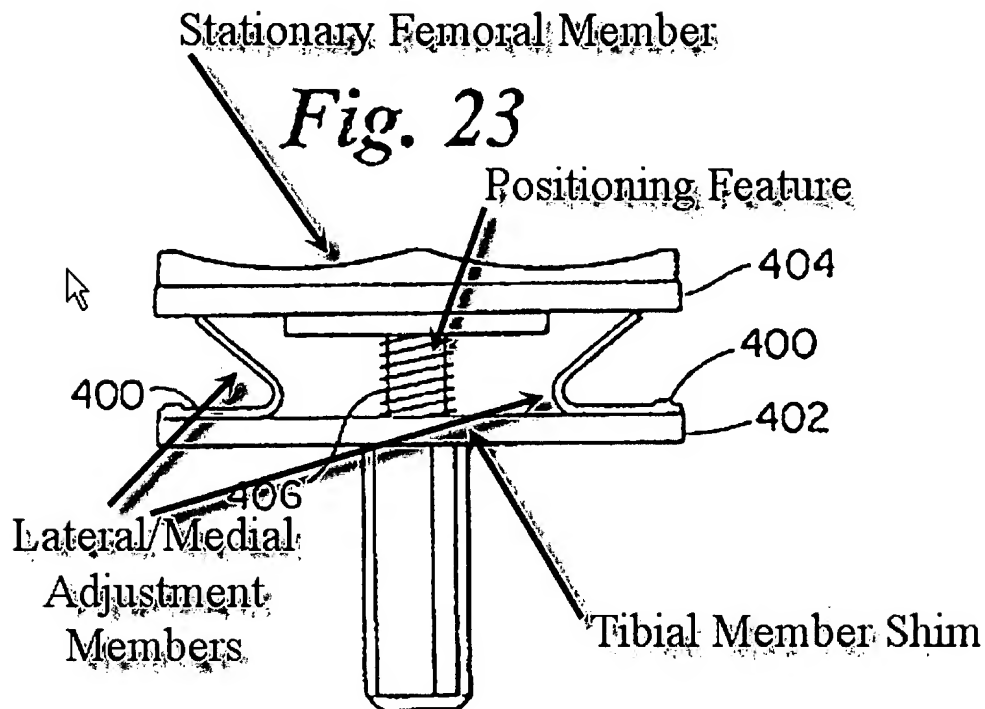
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-19, 21-22, 28, 30-33, 35-40, 42-53, 55-59, 61-62, 70-73, 75-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Gustilo et al. (U.S. Patent No. 5,733,292).

Gustilo et al. disclose a device comprising a stationary femoral member, an adjustable femoral member movably coupled with the stationary member that allows the knee to move through a range of motion (see Figure, next page). The adjustable member comprises a positioning feature. The adjustable member comprises a lateral adjustment member, and a medial adjustment member. The adjustment members are springs. The adjustment member comprises a distal femoral portion and a posterior condylar portion, the posterior condylar portion comprises a lateral and medial portion. The distal femoral portion and condylar portions comprise one piece. The stationary member comprises a distal femoral plate, and a posterior condylar member having a medial and lateral member, all comprising one piece. The adjustable femoral member comprises a self-adjusting member. The self-adjusting member comprises a spring-loaded member. The self-adjusting member adjusts relative to the stationary femoral member. The positioning feature on the adjustable member is a surface feature. The adjustable femoral member is asymmetrically oriented relative to the stationary member (see FIG. 3, col. 9, lines 42-46). The stationary member is made of a hard polymer, i.e. plastic (see col. 9, lines 59-61, and the adjustable member is made of a metal (see col.

Art Unit: 3733

8, lines 65-end). The device also comprises a tibial member. The tibial member comprises a shim.



Claims 1, 20-25, 28-29, 41, 60-61, 63-65, 68-69 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Gustilo et al. (U.S. Patent No. 5,733,292).

In another embodiment, Gustilo et al. disclose a device comprising a stationary femoral member, an adjustable femoral member movably coupled with the stationary member, and a tibial member that allows the knee to move through a range of motion. The adjustable member comprises a positioning feature. The positioning feature on the adjustable member is two apertures (ref. #128), and the device further comprises a grasping feature (ref. #130) coupled to the adjustable femoral member. The adjustable

Art Unit: 3733

femoral member is asymmetrically oriented relative to the stationary member (see FIG. 3, col. 9, lines 42-46). The adjustable femoral member comprises a plurality of pre-adjusted femoral members (see different embodiments, e.g. FIG. 1 FIG. 25, FIG. 26) having different asymmetries relative to the stationary member. The tibial member comprises a plurality of tibial members having different thicknesses or heights (see tibial members of FIG. 5 and 15).

With regard to statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Gustilo et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892.



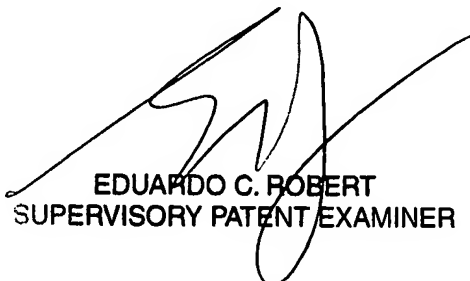
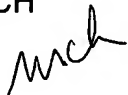
Art Unit: 3733

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER